REMARKS

The present communication responds to the Office Action mailed November 15, 2004. In that Office Action, the Examiner withdrew claims 10, 12-17, 21-24, 27-40 and 42 from consideration and rejected claims 54 and 56-62 under 35 U.S.C. 103(a) as being unpatentable over Balbierz in view of Cuschieri et al. and Brinkerhoff et al. The Examiner did not address the status of claims 43-53. None of the cited references, alone or in combination, disclose, teach or suggest use of an access port having an elastic self-closing diaphragm or accessing a fluid via an aspiration element associated with an elastic self-closing diaphragm and analyzing the fluid via the aspiration element, as required by independent claim 54.

Rejection Under 35 U.S.C. § 103

Claims 54 and 56-62 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Balbierz in view of Cuschieri et al. and Brinkerhoff et al. This rejection is traversed at least for the following reasons.

Balbierz

The Balbierz references discloses a method and apparatus for obtaining a lung biopsy with an apparatus capable of sealing tears within the lung and pleural space to reduce the risk of pneumothorax or pulmonary hemorrhage. The Examiner cites Balbierz for it's teaching of Figures 4B, 2 and 3A. The Examiner asserts that these figures disclose an access port for accessing a site, fluid delivery devices (28) capable of delivering a substance to the site, tissue aspiration collection device (26) to analyze material aspirated from the site, and a sensor (22) deployable into the site. The Examiner argues that the Balbierz access port is capable of performing the steps disclosed in the cited claims.

Balbierz teaches a lung biopsy apparatus:

> Referring now to FIG. 2, an embodiment of a lung biopsy apparatus 10 includes an elongated member or shaft 12 with a proximal end 14 and a distal end 16'. Distal end 16 may be sufficiently sharp to penetrate tissue including muscle, cartilage and bone. Shaft 12 may have one or more lumens 13 that may extend over all or a portion of its length. An energy delivery device, generally denoted as 18, is coupled to distal end 16'. Energy

> delivery device 18 is configured to be coupled to an energy or power source 20. A sensor 22 may be coupled to shaft 12 including distal end 16' and energy delivery device 18 ... Handpiece 24 can be coupled to tissue aspiration/collection devices 26, fluid delivery devices 28 (e.g. infusion pumps) fluid reservoirs (cooling, electrolytic, irrigation etc) 30 or power source 20 through the use of ports 24'. Tissue aspiration/collection devices 26 can include syringes, vacuum sources coupled to a filter or collection chamber/bag. Fluid delivery device 28 can include medical infusion pumps, Harvard pumps, syringes and the like. In specific embodiments, aspiration device 26 can be configured for performing thoracentesis which is a procedure for removing pleural fluid percutaneously. *Balbierz, Column 8, lines 16-65.*

Balbierz does not disclose analyzing fluids via an aspiration element associated with an elastic self closing diaphragm. While Balbierz discloses several sensors, none of these sensors analyze fluids via an aspiration element:

> Needle 16 can also include one or more sensors 22 disposed on or within needle 16 including within needle 16". Sensors 22 coupled to needle 16 can include pressure and/or flow sensors for sensing air, gas or liquid flow through the needle, or surrounding target tissue site 5' including tissue void space 5'". Pressure and/or flow sensors 22 can be configured to detect very minute pressure differences (e.g. 1 mm Hg or less) and/or flow rates so as to detect leaks before a pneumothorax develops. In another embodiments sensor 22 can be configured to detect the presence of a volume of void space 5'" created by the collection of sample 5" or other event. In these and related embodiments, sensor 22 can be an optical sensor or an ultrasound sensor or transducer either of which can be configured to provide an image of void space 5'" or otherwise detect its presence through differentiation of tissue properties created by the void space (e.g. optical or acoustical density and the like). *Balbierz, Column 12, lines 39-55.*
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> Also, electrode 18 can include one or more coupled sensors 22 to measure temperature and impedance (both of the electrode and surrounding tissue), voltage and current other physical properties of the electrode and adjacent tissue. Sensors 22 can be at exterior surfaces of electrodes 18 at their distal ends or intermediate sections. *Balbierz, Column 16, lines 1-6.*
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> Turning to a discussion of sensors, the use of one or more sensors 22 coupled to the introducer, energy delivery devices, deployable member and biopsy needles and permits accurate measurement of temperature at tissue site 5' in order to determine, (i) the extent of cell necrosis, (ii) the amount of cell necrosis, (iii) whether or not further cell necrosis is needed and (iv) the boundary or periphery of the ablated tissue mass ... Sensor 22 can be selected to measure temperature, tissue impedance or other tissue property described herein to permit real time monitoring of energy delivery. This reduces damage to tissue surrounding the targeted mass to be ablated. By monitoring the temperature at various points within and outside of the interior of tissue site 5', a determination of the selected tissue mass periphery can be made, as well as a determination of when cell necrosis is complete ... Sensor 22 can be of conventional design, including but not limited to

> thermal sensors, acoutiscal sensors, optical sensors, pH sensors, gas sensors, flow sensors positional sensors and pressure/force sensors. Thermal sensors can include thermistors, thermocouples, resistive wires, optical sensors and the like. A suitable thermal sensor 22 includes a T type thermocouple with copper constantene, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like. Acoustical sensors can include ultrasound sensors including piezoelectric sensors which can be configured in an array. Pressure and force sensors can include strain gauge sensors including silicon-based strain gauges. Optical sensors can include photomultipliers and micro-machined optical fibers. Gas sensors can include O2 sensors such as Clark electrodes, CO2 sensors and other electrochemical based sensors known in the art. Flow/velocity sensors can include ultrasound sensors, electromagnetic sensors and aneometric sensors which can be configured to detect both liquid and gaseous flows. Positional sensors can include LVDT's, and Hall effect sensors. Other sensors which can be employed impedance sensors, antibody-based sensors, biosensors (e.g. glucose) and chemical sensors. In various embodiments one sensor can be configured to detect multiple parameters or one or more sensors can be coupled together. *Balbierz, Column 17, line 51 – Column 18, line 40.*

There is no disclosure, teaching, or suggestion of accessing a fluid via an aspiration element associated with an elastic self-closing diaphragm and analyzing the fluid via the aspiration element, as required by independent claim 54, as amended.

The Examiner concedes that the Balbierz reference does not disclose use of an access port having an elastic self-closing diaphragm. The Examiner asserts that the use of self-closing diaphragms in an access port is conventional in the art as evidenced by the teachings of Cuschieri et al. and Brinkerhoff et al.

Cuschieri et al.

The Cuschieri reference discloses an extracorporeal pneumoperitoneum access bubble. The Examiner cites Cuschieri for the use of self-closing diaphragms in an access port.

Cuschieri explains the use of the access bubble device as being used to provide access to organs during laparoscopic procedures:

> The medical device according to the present invention provides an extension of the pneumoperitoneum during laparoscopic procedures which allows improved access to the organ or organs being worked upon. The device also allows the simultaneous, multiple entry and withdrawal of a wide range of surgical instruments through a single incision in the abdominal wall, and may hence reduce the overall number of puncture sites needed for the procedure. The device can include means for allowing access of the surgeon's

> hand or hands to the pneumoperitoneum and the device can be of a transparent material which allows clear observation during the surgical procedure. *Cuschieri, Column 2, lines 52-63.*

The Cuschieri device includes an enclosure and a deploying means which can be inserted into a trocar puncture site.

> The deploying means then expands beneath the inner surface of the abdominal wall. By applying a gentle lifting force on the enclosure, the deploying means forms a seal with the abdominal wall allowing insufflation gas in the abdominal cavity to inflate the enclosure into a "balloon" shape. Once inflated, the internal gas pressure in the abdominal cavity maintains the device in a stable shape. The device includes one or more access openings which allow access to the interior of the enclosure, and hence the abdominal cavity. *Cuschieri, Column 3, lines 16-26.*
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> The deploying means preferably returns to its original shape after being elastically deformed by an external force. *Cuschieri, Column 4, lines 7-8.*

It is not clear that Cuschieri fundamentally even teaches an access port. However, even if one were to interpret the access bubble in its entirety as a port implanted in the body, Cuschieri does not teach an elastic self-sealing diaphragm associated with the access bubble. Cuschieri teaches a number of valves through which objects may pass:

> In a preferred embodiment, the access opening comprises one or more iris valves 11 constructed from a pair of rings 12 fixed or rotatable with respect to each other and connected to opposite ends of a tube 13 of an elastic material. As shown in FIGS. 3 a-d, the tube 13 can be supported at each end thereof by rings 12 and by twisting the rings 12 in opposite directions (FIG. 3b), an iris valve is formed (FIGS. 3c-d) ... The iris valve 11 may be a fixed iris valve 14 wherein the valve is always biased closed due to the resilient tube 13 which is held in a twisted condition, as shown in FIGS. 1 and 5. The iris valve 11 may also be an adjustable valve 15 wherein one ring is rotatable with respect to the other ring, as shown in FIGS. 1 and 5. The fixed iris construction allows access of relatively small surgical instruments or tools, e.g., 5 to 20 mm diameter, due to the elasticity of the tube material which allows the body of the instrument to be inserted through the center of the iris ... For larger objects, such as a hand, it may be desirable to use the adjustable iris valve 15. In this instance, the valve 15 can be quickly opened wide enough to allow passage of a hand and then closed around the wrist of the surgeon to prevent loss of pneumoperitoneum ... Other valve constructions which can be used for the access opening 5 include a re-enterable valve constructed from self-sealing gels. Such gels allow the penetration of objects, yet on withdrawing the invading device they seal behind it as it is withdrawn. Suitable materials include, for example, gels based on lightly cross-linked silicone, vegetable, or fish oils, or blends thereof. A valve somewhat like a multi-leaved flapper valve may also be used. Further, for relatively small diameter

> instruments, it is possible to use an elastomeric insert which contains a pinhole. This allows access to the interior of the enclosure but such a pinhole type valve could be limited with respect to the size of objects which can pass therethrough yet maintain peritoneum after the objects are removed from the pinhole. Other valving systems such as duck bill valves, etc., may also be used. *Cuschieri, Column 4, lines 15-60.*

None of these valves are elastic and self-sealing.

Thus, Cuschieri does not correct the fundamental deficiencies of the Balbierz reference in making obvious claims 54 and 56-62. As stated above, Balbierz does not disclose, teach or suggest accessing a fluid via an aspiration element associated with an elastic self-closing diaphragm and analyzing the fluid via the aspiration element, as required by independent claim 54, as amended. Nor does Balbierz reference disclose, teach or suggest use of an access port having an elastic self-closing diaphragm. Cuschieri similarly does not disclose, teach or suggest an access port having an elastic self-closing diaphragm or accessing a fluid via an aspiration element associated with an elastic self-closing diaphragm and analyzing the fluid via the aspiration element.

Brinkerhoff et al.

The Brinkerhoff reference discloses an endoscopic surgical sealing device. The device is partially inserted into an abdominal opening in a deflated state, and then inflated to provide a seal for obstructing the passage of gas from the abdominal cavity during endoscopic surgery. The Examiner cites Brinkerhoff for the use of self-closing diaphragms in an access port.

The applicants respectfully disagree with the Examiner's interpretation of the Brinkerhoff reference. Brinkerhoff does not teach a self-closing diaphragm. To provide a seal, the inflatable sealing device 40 includes a central lumen 46 that may be closed by inflating an inflatable toroidal section 42 using an inflation and deflation means 44:

> The trocar opening 49 into the body cavity 48 is sealed against leakage of gas by the closing of the central lumen 46 of the sealing device 40 when the sealing device 40 is inflated as illustrated in FIG. 5. The central lumen 46 of the sealing device 40 is easily opened by inserting an endoscopic instrument 50. The gas sealing is accomplished between the endoscope instrument 50 and the trocar 41 as shown in FIG. 6 by inflation pressure inside the toroidal section 42 of the sealing device 40 forcing the central lumen

> 46 to close tightly around the movable endoscopic instrument 50. *Brinkerhoff, Column 5, line 65 – Column 6, line 2.*

Thus, while the Examiner asserts that Brinkerhoff teaches a self-closing diaphragm, Brinkerhoff explains that a trocar is naturally sealed by the elastic nature of the tissue in the abdominal wall. The elastic nature of tissue in the abdominal wall in sealing a trocar does not provide a self-closing diaphragm of a port body. Brinkerhoff also teaches providing a seal by inflating a toroidal section of a sealing device. However, a section of a device that requires inflation for providing a seal does not provide a self-closing diaphragm of a port body.

Brinkerhoff describes the use of the inflatable sealing device of Figure 5 in a trocar during a laparascopic procedure to provide a seal around an endoscopic instrument:

> The function of the sealing device in this embodiment is illustrated in FIGS. 5 and 6. In the laparoscopic procedure, the trocar 41 is inserted through the abdominal wall 47 into the abdominal cavity 48 to allow instruments to pass through the abdominal wall 47 to accomplish the procedure while the abdominal cavity 48 is under gas pressure. The trocar 41 is naturally sealed at the abdominal wall 47 by the elastic nature of the tissue in the abdominal wall 47. *Brinkerhoff, Column 5, lines 57-65.*

The applicants respectfully submit Brinkerhoff does not correct the fundamental deficiencies of the Balbierz reference in making obvious claims 54 and 56-62. As stated above, Balbierz does not disclose, teach or suggest accessing a fluid via an aspiration element associated with an elastic self-closing diaphragm and analyzing the fluid via the aspiration element, as required by independent claim 54, as amended. Nor does Balbierz reference disclose, teach or suggest use of an access port having an elastic self-closing diaphragm. Brinkerhoff similarly does not disclose, teach or suggest an access port having an elastic self-closing diaphragm or accessing a fluid via an aspiration element associated with an elastic self-closing diaphragm and analyzing the fluid via the aspiration element.

Conclusion

At least for the reasons given above, the applicants respectfully submit that claims 54 and 56-62 are patentable over Balbierz in view of Cuschieri et al. and Brinkerhoff et al. The applicants thus respectfully request reconsideration of the rejection of claims 54 and 56-62 under

35 U.S.C. 103(a) as being unpatentable over Balbierz in view of Cuschieri et al. and Brinkerhoff et al.

This application now stands in allowable form and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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